

COSTING METHODOLOGY ISSUES**CM1****ESTIMATING THE COSTS AND OUTCOMES FOR DIFFERENT DISEASE MANAGEMENT STRATEGIES: A CASE STUDY OF CYTOMEGALOVIRUS INFECTION AND DISEASE**Mauskopf J¹, Annemans L², Richter A¹, Chulay J³, Maclaine G³¹Research Triangle Institute, Research Triangle Park, NC, USA;²HEDM, Belgium; ³Glaxo Wellcome, Research Triangle Park,

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This workshop will describe a methodology for estimating the costs and outcomes for a disease under different disease management strategies. The methodology uses a combination of published data, physician interviews, national databases, and standard reference sources and can be applied in multiple countries. The methodology includes several steps including: (1) a review of the published literature on disease epidemiology, treatment and prevention efficacy, and disease management recommendations; (2) interviews with physicians managing the disease to determine their treatment practices and to ask them about the health care products and services used by their patients; (3) use of standard references and national data bases to validate the health care use data and to obtain unit costs for health care services; (4) validation of the results using patient data bases; and (5) combination of all the data using spreadsheet and decision tree software. The methodology will be illustrated using the example of cytomegalovirus (CMV) infection and disease in renal transplant patients. Three disease management strategies are compared, prophylaxis (ganciclovir), testing for virus (direct antigen testing and culture) and pre-emptive therapy (ganciclovir), and treatment only (ganciclovir with or without immune globulin). The cost and outcome estimates were obtained for the US and the UK. The results can be applied by health care decision makers and providers to understand the impact of different current and anticipated disease management strategies on costs and patient outcomes.

CM2**CLINICAL INTERVENTION ASSESSMENT: IMPLEMENTATION OF DEFAULT VALUES FOR EXPEDITING THE CALCULATION OF COST SAVINGS AND COST AVOIDANCES**

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Our Pharmacy department has previously described the implementation of a clinical documentation system. This computerized system is utilized by pharmacists in both the inpatient and ambulatory care practices throughout our institution, and allows for the comprehensive documentation of clinical activities. A major goal of the sys-

tem is to accurately capture cost avoidances as well as cost savings attributed to our staff through their day to day interactions with the patients whom they serve. The method utilized for calculating cost avoidances as previously been described, relies on hospital-specific DRG data as a proxy in order to better quantify the impact of our clinical interventions on the patients' length of stay. During the initial 5,000 interventions, a series of weekly meetings was initiated where clinical as well as administrative staff met to manually review interventions in order to quantify cost savings as well as cost avoidances. However, a significant rate limiting step for the process was the amount of time necessary to accurately evaluate the numerous interventions. Currently, more than 40,000 interventions have been entered into our electronic database. The growing numbers of interventions documented have necessitated the development of a series of drug specific defaults which allow for the automatic calculation of cost savings and cost avoidances based on our historical data. This method (1) offers a more streamlined approach to the calculation of these important outcome data; (2) decreases the time required by the financial assessment committee to evaluate the economic impact of clinical interventions; and (3) provides a more cost-effective method of obtaining this important data to provide to hospital administrators, clinical decision makers, and department staff.

CM3**MULTIVARIABLE METHODS FOR MEASURING TREATMENT COSTS IN RANDOMIZED TRIALS**

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As treatment costs are increasingly determined from individual level cost data, the number of proposed multivariable methods for use in this analysis has multiplied. These methods involve estimation of multivariable cost functions that yield predictions at the individual level, conditional on interventions, patient characteristics, and other factors. What are these methods, how are they used properly, and what are the circumstances when one method is preferred over others? The purpose of this workshop will be to develop skills in conducting multivariable analysis of cost data from randomized trials. We will instruct participants in the use of ordinary least squares regression techniques and survival analysis techniques. We will discuss how non-normal cost data and censored cost data are properly and improperly handled in these methods. Participants will learn when it is appropriate to use log transformation of costs in their analysis and how to estimate unbiased treatment costs using smearing techniques. Participants will also learn how to apply the Cox proportional hazard model to analysis of costs. How does one determine which model is best given the circumstances? We will develop concepts important for evaluating the superior model: predictive validity and adherence to assumptions for unbiased estimators. We will present re-

sults from a simulation designed to evaluate how well the various methods perform under different circumstances. Those who want to learn the techniques of multivariable cost analysis and develop criteria for choosing the best technique will benefit from this workshop. Participants who would benefit include analysts of cost data and those who want to increase their understanding of the literature of economic evaluation.

CM4

USE OF UB-92S AND MEDICARE COST REPORTS IN A LARGE, MULTI-CENTER RANDOMIZED TRIAL: THE PURSUIT EXPERIENCE

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The conversion of hospital bill charges using Uniform Bill (UB)-92s and Medicare Ratios of Cost to Charges (RCCs) to costs in economic analyses is one of the most efficient, accurate and accessible ways of measuring resource consumption for US hospitalizations.

OBJECTIVES: We used the hospital bill charge to cost conversion method in our analysis of over 3,000 patients with 4,700 hospital bills in the recently completed PURSUIT pharmacoeconomic substudy. Using the PURSUIT trial experience as a model, this workshop will provide a detailed explanation of the cost to charge conversion methodology. We will begin with a detailed procedure for incorporating this method of cost collection into a clinical trial's overall protocol and case report form. We will explain how to ensure collection of bills for all patient hospitalizations and procedures; how to interpret the UB-92; how to extract charges from the UB-92 and convert those charges into costs using each hospital's Medicare Ratio of Cost to Charges. This workshop will also explore mechanisms for ensuring successful compliance across sites in large, randomized clinical trials including inservice training for coordinators and common obstacles to successful and complete collection. In addition, the workshop will explore the limitations and strengths of this method compared with other cost collection methods. This workshop will be particularly useful to project leaders, clinical trial coordinators, and database managers interested in performing economic analyses as part of larger clinical trials or as stand-alone endeavors.

CM5

DISCOUNTING HEALTH BENEFITS IN PHARMACOECONOMIC ANALYSES: IS IT JUSTIFIED?

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Most guidelines for economic analysis call for discounting of health benefits. This major methodological point has rapidly moved from debate to common practice. Yet,

the powerful effect that discounting can have on an analysis means that it may become the dominant factor in a therapeutic decision. These grave implications should cause pharmacoeconomic analysts to take pause. This workshop will examine the implications of discounting, its rationale and counterpoints, in an effort to establish whether discounting of benefits is justified or not. Topics covered will be: The Basis for Discounting; The Logical Implications of Discounting; and Discounting: A New Approach. Pharmacoeconomics is a fast evolving field. New thought should continually be put into refining its methodology. Ultimately, the aim of this workshop is to take time to rethink the various issues that surround discounting of health benefits.

CM6

THE USE OF PATIENT SELF-REPORTS TO COLLECT HEALTH CARE RESOURCE UTILIZATION DATA

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This workshop offers a critical examination of the use of patient self-reports in pharmacoeconomic evaluations. This session is directed at individuals in pharmaceutical firms, CROs, and consultancy companies who are responsible for the design and conduct of pharmacoeconomic evaluations. The workshop advances recent research by concentrating on how the method of data collection in prospective clinical economic evaluations may influence study findings. Scant attention has been paid to the fact that the high level of internal validity found in prospective studies may be compromised by the application of inappropriate methodologies to data collection. Particular attention in this workshop is placed on how validity may be affected by the elapsed time between admission and self-reporting, salience of a treatment event and perceived social desirability of a condition. As part of this workshop we will highlight areas where estimates based on patient self-reports lead to either reliable or suspect values. In particular, we examine the areas of hospitalization, outpatient consultations, medication use and indirect costs. The impact that patient self-reports have on cost-effectiveness ratios is also discussed. Attendees at this workshop will gain an understanding of current methodological shortcomings in this area and researchers and readers of pharmacoeconomic studies will gain the skills necessary to better design studies and evaluate the validity of, and potential for bias in cost-effectiveness analyses.